

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
Chada et al.

Serial No.: 10/017,472

Filed: December 7, 2001

For: METHODS OF TREATMENT
INVOLVING HUMAN MDA-7

Group Art Unit: 1633

Examiner: Li, Qian, Janice

Atty. Dkt. No.: INGN:097US

**DECLARATION OF SUNIL CHADA, RAJAGOPAL RAMESH
AND ABNER MHASHILKAR UNDER 37 C.F.R. § 1.132**

We, Sunil Chada, Rajagopal Ramesh, and Abner Mhashilkar hereby declare as follows:

1. We are the inventors of the subject matter of all claims currently pending in the present patent application, U.S. Patent Application Serial Number 10/017,472 ("the present application").
2. Sunil Chada and Abner Mhashilkar are also co-inventors of the subject matter of the claims currently pending in U.S. Patent Application Serial Number 09/615,154 ("the '154 application").
3. We understand that claims 1-4, 7-23, 25, 35-43, and 68-77 of the present application have been rejected under 35 U.S.C. § 102(f) as anticipated by the '154 application. The Patent and Trademark Office Examiner asserts that the claimed subject matter of the present application is disclosed in the '154 application.
4. The '154 application mentions the inhibition of angiogenesis in two locations in the specification. The first location is the paragraph at page 14, lines 16-21, which recites:

Other methods of the invention include treating a subject with a tumor by administering to the subject a nucleic acid molecule comprising a human mda-7

gene under the control of a promoter in an amount effective to inhibit angiogenesis around the tumor. Such methods may also include steps to evaluate the level of angiogenesis inhibition. It is contemplated that other embodiments of treatment described herein may be implemented with these methods.

The second location is the paragraph at page 118, lines 23-28, which describes an experiment in which subcutaneous tumors treated with Ad-mda-7 demonstrated fewer numbers of blood vessels, as determined by analysis of CD31 expression, as compared to tumors treated with Ad-Luc or no treatment.

5. The paragraphs at page 14, lines 16-21, and page 118, lines 23-28, of the '154 application describe the work of Sunil Chada, Rajagopal Ramesh, and Abner Mhashilkar. Sunil Chada, Rajagopal Ramesh, and Abner Mhashilkar conceived of and designed the study described at page 118, lines 23-28, of the '154 application. The study itself was performed in Rajagopal Ramesh's laboratory at the M.D. Anderson Cancer Center in Houston, Texas, under a sponsored research agreement with Introgen Therapeutics, Inc. From this study we concluded that a subject with a tumor could be treated by administering to the subject a nucleic acid molecule comprising a human mda-7 gene under the control of a promoter in an amount effective to inhibit angiogenesis around the tumor, as described at page 14, lines 16-21, of the '154 application. Bob Schrock, who is identified as an inventor on the '154 application, did not contribute to the above-mentioned study of inhibiting angiogenesis described in the '154 application, but contributed to other aspects of the '154 application.

6. I hereby declare that all statements made of my own knowledge are true and all statements made on information are believed to be true and further that the statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both under § 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of this application or any patent issued thereon.

Date

March 29, 2007
Date

Sunil Chada, Ph.D.

R. Ramesh
Rajagopal Ramesh, Ph.D.

Date

Abner Mhashilkar, Ph.D.